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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,051	TANAKA ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 5-14* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2005 and 8/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to papers filed August 27, 2007. Applicants' response to the restriction requirement of August 3, 2007, has been entered. No claims were cancelled, amended or newly added. Currently, claims 2 and 5-14 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group I, (claims 2, 5-7 and 11), drawn to a GLAST knockout mouse deficient in the function of an endogenous GLAST gene, is acknowledged.

The traversal is on the grounds that the PTO has failed to establish a serious burden for search and examination upon which a restriction requirement must be based. Applicants' arguments have been fully considered, but are not found to be persuasive, because Applicants have relied on U.S. restriction practice in a case where restriction has been properly applied under rules for Unity of Invention. PCT Rule 13.2, as it was modified effective July 1, 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. Thus, burden is not germane to restriction under rules of Unity of Invention. In the instant case, the special technical feature shared by the Groups (i.e. a GLAST knockout mouse) is anticipated by the prior art of Harada et al., as set forth on p. 2 of the previous office action dated 8/3/2007. The restriction under PCT rules13.1 and 13.2 is proper, and Applicants have not provided any evidence or arguments that Harada et al. has been improperly applied. Furthermore, according to MPEP 1893.03(d), any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

The restriction requirement is deemed proper, maintained and made FINAL. Claims 8-10 and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected subject matter, there being no allowable generic or linking claim.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Applicant timely responded to the restriction (election) requirement in the Papers filed August 27, 2007. Claims 2, 5-7 and 11 are under current examination.

Information Disclosure Statement

The information disclosure statement filed 10/12/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been fully considered, since several references were not present in the instant application. Applicant is required to provide copies of the missing references to be considered by the examiner.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is ambiguous. The claim encompasses a GLAST knockout mouse wherein the genetic background is the same as the genetic background of a C57BL/6 strain mouse. As the GLAST knockout mouse contains a genetic disruption of the endogenous GLAST gene by insertion of a transgene, it must necessarily contain a genetic variation in its genome. Thus, it is

not clear how the mouse may be at once a knockout and have the same genetic background of a C57BL/6 strain mouse (i.e. wild type).

Claim 5 is directed to a GLAST knockout mouse wherein the genetic background is the same or substantially the same as the genetic background of a C57Bl/6 strain mouse. The claim lacks an antecedent basis for "the genetic background". Amendment of the claim to recite "the genetic background of said mouse" would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Watase et al. (Eur. J. Neurosci. 10:976-988; 1998).

Claim 11 is directed to a homozygous or heterozygous GLAST knockout mouse produced by the production method according to claim 9. As such, the claim is a product by process claim. Further the claim does not recite a phenotype, or any particular genetic background for the knockout mouse.

MPEP 2113 states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Watase et al. teach the inactivation of the mouse GLAST gene, resulting in motor discoordination and susceptibility to cerebellar injury (Title and Abstract). The production of GLAST mutant mice by targeted disruption of exon 6 with insertion of a Neo gene is described on p. 978, first column and Fig. 1, p. 979, and include the generation of heterozygous and homozygous mutant mice containing the targeted GLAST gene (first column, p. 978).

Therefore by teaching all the limitations of claim 11, Watase et al. anticipate the instant invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, and 5-7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Watase et al. (Eur. J. Neurosci. 10:976-988; 1998), in view of Chitnis et al. (J. Clin. Invest. 108(5):739-747; 2001).

The claims encompass a transgenic GLAST knockout mouse deficient in the function of an endogenous GLAST gene, wherein a neomycin-resistant gene is inserted into exon 6 of said GLAST gene, and wherein the genetic background of said knockout mouse is substantially the same as the genetic background of a C57BL/6 strain mouse.

Watase et al. describe the inactivation of the mouse GLAST gene (Abstract) following the targeted disruption of the endogenous mouse GLAST gene in ES cells, the generation of chimeric mice by injecting targeted ES cells into C57BL/6 blastocysts and germline transmission of the targeted mutation in the GLAST gene to generate homozygous and heterozygous mutants (first column, p. 978). The production of GLAST mutant mice by targeted disruption of exon 6 with insertion of a Neo gene is described on p. 978, first column and Fig. 1, p. 979, and include the generation of heterozygous and homozygous mutant mice containing the targeted GLAST gene (first column, p. 978).

While Watase et al. do not describe the details of genetic crosses or backcrosses used to derive the heterozygous and homozygous GLAST knockout mice, such cross breeding was known in the art of transgenic mouse production at the time, and must have necessarily been employed to produce the knockout mice. Nonetheless, at least the generation of GLAST mutations in a C57BL/6 chimeric background are explicitly taught by Watase et al.

Chitnis et al. describe the effect of targeted disruption of mouse STAT genes in knockout mice (Abstract). Additionally describe the backcross of said knockout mice onto a C57BL/6 background for at least ten generations (first column, p. 740).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Watase et al. and Chitnis et al. (as both describe mice with targeted disruption of endogenous genes in a C57BL/6 genetic background), with a reasonable expectation of success, at the time of the instant invention. A person of skill in the art could utilize the multigenerational backcross to a C57BL/6 genetic background to produce an inbred GLAST knockout mouse having less genotypic and phenotypic background variation, which amounts to variation of known methods in the same field as a matter of design choice, that are predictable to one of ordinary skill in the art. Applicants should note that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82USPQ2d 1385 (2007).

Regarding the limitations of claim 2, wherein the GLAST knockout mouse has an intraocular pressure that is not greater than 21mHg and the number of cells in the retinal ganglion is reduced by at least 20%, it should be noted that said limitations are properties inherent to the transgenic knockout mouse produced by the methods of Watase et al. and Chitnis et al., wherein the genetic background is substantially the same as the genetic background of a C57BL/6 strain mouse. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

As indicated in MPEP 2112, the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The

inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

Claims 2, 5-7 and 11 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, A.U. 1633

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